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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/156,952	09/18/98	OSTGAARD	CYM-025

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EXAMINER

BEX, P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/20/01

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Best Available Copy

Office Action Summary

Application No.

09/156,952

Applicant(s)

OSTGAARD ET AL.

Examiner

P. K. Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 12-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

DETAILED ACTION

1. The cancellation of claims 9 and 11 in the Amendment filed June 13, 2000 was mistakenly not acknowledged in the previous Office Action, however it was entered into the record at the time of filing.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8, 10, 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, it is vague and indefinite as to how the "anti-rotation" lugs prevent rotation of the vial without the use of a storage tray and/or vial sleeve, as disclosed in the specification on page 8, lines 23-26

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1743

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-8, 10, 12-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Julian (USP 3,825,143).

Moore teaches a sample vial for use in an automated test apparatus comprising a body with an outer surface, an open end, a closed end, a cap 34 releasably engagable with the body, the cap comprising an outer surface and a torque pattern (Fig. 1 & 3) on the cap outer surface, the torque pattern comprising a plurality of radially disposed ribs 64, and seals 54, 98 disposed between the body and the cap so as to be capable of forming a substantially fluid-tight seal therebetween. Moore does not teach the use of at least one anti-rotation lug about the body outer surface. However, Julian does teach the use of at least one anti-rotation lug 19 about the body outer surface (column 2, lines 18-37, Figs. 1-6).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the sample vial of Moore the lugs as taught by Julian, in order to ensure that the cap remains tightly in place on the container and cannot be removed even by carrying out the unexpected movement (column 1, lines 2-38).

Moore teaches sample fluid level indicia 108 comprising an upper fill line and a lower fill line on the outer surface of the vial body (Fig. 1).

Moore teaches a first alignment marker 110 on the body on the cap and a second alignment marker 108 on the body (column 7, lines 24-40).

Moore teaches a cap comprising first screw threads 62 (Fig. 4) and a second mating screw thread 80 on the body (Fig. 1).

Moore does not explicitly teach the use of the body and cap made from polypropylene, however would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the body and cap from an inert material, such as polypropylene, in order to ensure that the sample inside the vial will not react with the container or cap. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Moore teaches a fluid-tight seal formed between the body and the cap (column 6, lines 41-61). However, Moore does not disclose the range of torque between 5 and 50 inch-pound of torque applied to the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in the invention of Moore the range of torque between 5 and 50 inch-pound of torque applied to the cap in order to ensure the cap and vial are properly sealed and prevent the leakage of a sample or air from the vial. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Julian (USP 3,825,143), as applied to claim 23 above, and further in view of Neeley *et al* (USP 5,164,575).

Moore and Julian as previously discussed, does not teach a sample indicia comprising a bar code. However, such a means for identifying kinds of sample vials is considered

Art Unit: 1743

conventional and usually required in the automatic analyzing art, see Neeley *et al.* Neeley *et al* teaches a sample indicia comprising a bar codes 7 & 51 (column 6, lines 46-68, Figs 4-5 & 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the modified apparatus of Moore, a bar code on the sample vial, as taught by Neeley *et al*, in order to identify the sample and make sure the proper sample is matched up with the patient (columns 2-3).

Response to Amendment

8. The reply filed on January 8, 2001 is defective because the amendment fails to underline below the matter added, in this case the limitation "anti-rotation" was introduced without being underlined in claim 1. The amendment to the claims should be made in accordance with 37 CFR 1.121(a)(2)(ii) which states:

(ii) Claim cancellation or rewriting: A claim may be amended by directions to cancel the claim or by rewriting such claim with underlining below the matter added and brackets around the matter deleted. The rewriting of a claim in this form will be construed as directing the deletion of the previous version of that claim. If a previously rewritten claim is again rewritten, underlining and bracketing will be applied relative to the previous version of the claim, with the parenthetical expression "twice amended," "three times amended," etc., following the original claim number. The original claim number followed by that parenthetical expression must be used for the rewritten claim. No interlineations or deletions of any prior amendment may appear in the currently submitted version of the claim. A claim canceled by amendment (not deleted and rewritten) can be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

Response to Arguments

9. Applicant's arguments filed January 8, 2001 have been fully considered but they are not persuasive.

Applicant argues that Julian (USP 3,825,143) use of lugs 19 fail to restrict the movement of the container in response to the movement of the lid. Applicants' arguments are not commensurate in the scope of the claimed invention. The claims of the instant application are restricted to the structure of the sample vial, not the intended use of the vial. Further, applicant

Art Unit: 1743

has not included in the instant claims the limitation of a storage tray and/or vial sleeve which act in concert with the lugs to prevent the rotation of the vial, without such a limitation is it not clear as to how lugs by themselves prevent such a rotation. Further, applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore the lugs of Julian clearly meet the structural limitations of the claims.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Julian teaches that the use of lugs function to ensure that the cap remains tightly in place on the container and cannot be removed even by carrying out the unexpected movement (column 1, lines 2-38).

Conclusion

10. No claims allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1743


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


P. Kathryn Bex
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03/19/01


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